## CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER: 20-603/S-001, S-002, S-003** 

## **APPROVED LABELING**

MMP ORTANT: Read all product information beloin lesing. Keep this box for important information. This product is intended for use by children only.

ACTIVE INGREDIENT: Ibeprofen USES: For Tomperary:

- Reduction of lever
   Reduction of leve DIRECTIONS:
- . Find right dose on chart below. If possible, use weigh to dose; otherwise use age. . Measure dose with dropper provided. Use enclosed
- Repeat dose every 6—8 hours, If needed. Do not use more than 4 times a day.

SHAKE WELL BEFORE USING

Under 24	Under 2	Consult Dector
24-35	2-3	2 Dropportuls (2 x 1.25 mL)

#### WARNINGS

ASPININ SENSITIVE CHILDREN:

Although this product does not contain aspirin, it may cause a severe reaction in people allergic to aspirin. Children's Motrin may cause:

- shock (low blood pressure) allergy
   shortness of breath swelling
- \* shortness of breath \* swemmy of the tace Children's Mortin can cause serious reactions, similar to those listed above, requiring lumination medical attention. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Mortin or other pain reliever/lever reducer.

(See Side Panel to the Right for Additional Warnings)

WARNINGS (cooffolia) CALL YOUR DOCTOR IF:

Your child is under a doctor's care for any serious condition or is taking any other drug. Your child has problems or serious side effects from taking lever reducers or peln relievers.
Your child does not get any relief within first day (24 hours) of treatment, or pain or lever

gets worse.
Redness or swelling is pres in the painful area.
Sore throat is severe, lasts

for more than 2 days or occurs with lover, headache, rash, nauses or vomiting. Any new symptoms appear.

With any other product that contains ibuproton, or any other pain reliever/lever reducer, unless directed by

a doctor. For more than 3 days for fever or pain unless directed by a doctor.

by a socior.
For stormach pain unless
directed by a doctor.
If your child is dehydrated
(significant field loss) due to
continued vorniting, diarrhea
or lack of field intake.

Miscalls better If plastic bottle wrap imprinted with "Safety SealO" is broken.

See Opposite Side Panel or Additional Warnings)

Children's Drops

BUPROFEN ORAL SUSPENSION Fever Reducer Pain Refever

For Ages 2-3

# Children's Drops

BUPROFEN ORAL SUSPENSION (Inheridolp) Tur 97 Field Sun Officerun)

Fever Reducer/Pain Reliever Lasts up to 8 hours



BERRY ELAVORED DROPS

WARNINGS (confided) MPORTANT:

Koop this and all drugs out of the reach of children, in case of accidental everyone, sock professional assistant or contact a poleon control cealer law

coacer humadalety.

If stomach upset occurs
while taking this product, give
with lood or milk. If stomach
upset gets worse or lasts, call
your doctor.

**An Questions or Comments?** Call toll free

**1-800-962-5357** 

Or ask your Pharmacist, **Doctor or Health Care** Professional.

See bottom of box for lot number and expiration date. 18"-30°C (50"-86"F)

Insultive legicalisats: Citric acid, cornstanch, artificial flavors, glycerin, polysorbete 80, purified water, sodiern benzoele, sorbitol, sucrose, xanihan gurn, FD&C Red #40

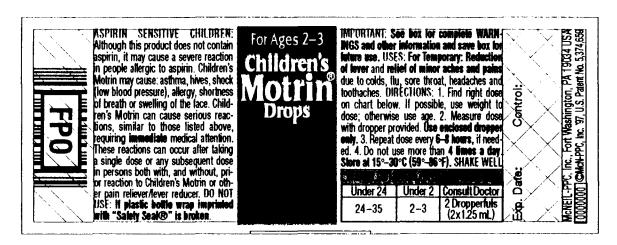
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MeMER. Consumur Products Co Division of McMER\_PPC, Inc. Fort Washington, PA 19834 USA CMCM-PPC, Inc. 97 U.S. Patent No. 5,374,659

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EXP:





WAANINGS (confinued)

CALL YOUR DOCTOR IF:

Your child is under a doctor's

care for any serious condition

or is taking any other drug. Your child has problems or

serious side effects from takin tever reducers or pain reflevers.
Your child does not get any relief within first day (24 hours) of treatment, or pain or lever

gets worse. Redness or swelling is present

Sore throat is severe, lasts for more than 2 days or occurs with lever, headache, rash,

nausea or vomiting. Any new symptoms appear.

With any other product that contains ibuprolen, or any other pain reliever/lever reducer, unless directed by

For more than 3 days for

For stomach pain unless

tever or pain unless directed by a doctor.

directed by a doctor.
If your child is dehydrated (significant fluid loss) due to

continued vamiling, diarrhea or tack of fluid intake.

See Opposite Side Panel or Additional Warnings)

If plastic bottle wrap imprinted with "Safety Seaf®" is broken.

in the painful area.

DO NOT USE:

a doctor.

Children's **Drops** IBUPPOFEN OR AL SUSPENSION

# Children's

\$0 mg per 1 25 ml (dropper10) -

Fever Reducer/Pain Rellever

fever Reducer Familie lever For Ages 2 – 3

IBUPROFEN ORAL SUSPENSION

Lasts up to 8 hours

BERRY-FLAVORED DROPS

0000-0000-00 EXP:

PONTANT: Meait an product information belore ing. Koop this box for important information. This educt is intended for use by children only. ACTIVE INGREDIENT; Ibuprolen. USES: For Tomporary
- Reduction of Sever Relief of wheer aches and pales due to colds, flu, sore throat, headaches and toothaches DIRECTIONS:

. Find right dose on chart below. If possible, use weight to dose; otherwise use age.

Measure dose with dropper provided. Use enclosed

dropper eaty. Repeat dose every 6—8 hours, if needed. . Do not use more than 4 times a day.

SHAKE WELL BEFORE USING

Af art		
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperluis (2 x 1.25 mL)

#### WARNINGS

ASPIRIN SENSITIVE CHILDREN:

Although this product does not contain aspirin, it may cause a severe reaction in people allergic to aspirin. Children's Motrin may cause:

- asthma

 shock (low blood pressure) - allergy
 enortness of breath - swelling of the face Children's Motrin can cause serious reactions, similar

hives

Circulars in victor can cause serious reactions, similar to those listed above, requiring transaction medical attention. These reactions can occur after taking a single dose or any sebequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain reliever/lever reducer.

(See Side Panel to the Right for Additional Warnings)

WARNINGS (continued)

If stomach upset occurs
while taking this product, give
with food or milk. If stomach

upset gets worse or lasts, call

Or ask your Pharmacist,

**Doctor or Health Care** Professional.

See bottom of box for lot number and expiration date.

Inactive Ingredients: Citrical acid, correstarch, artificial

Bavors, glycerin, polysorbate 80, purified water, sodium benzoete, sorbitol, sucrose,

xanthun gum, FD&C Red #40.

MicHEH. Consumer Products Co. Division of MicHEH. PPC, Inc. Feel Weshington, PA 19834 USA CRIcil-PPC, Inc. 97 U.S. Palant No. 5,374,850

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Store at mem temper 18"-30"C (50"-36"F)

ies or Comments?

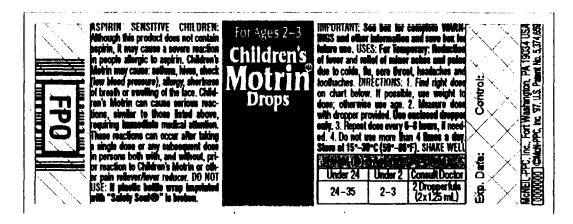
IMPORTANT:

your doctor.

Call toll free

1-800-962-5357





IMPORTANT: Read all product information before using. Keep this box for important information. This product is intended for use in children only.

ACTIVE INGREDIENT: Ibuprofen.

USES. For Temperary:
• Reduction of fover

Relief of minor actors and pains due to colds, liu, sore throat, headaches and toolliaches

DIBLUTIONS.

Shake well before using.
 Find right dose on chart below. It possible, use weight to

dose; otherwise use age.

3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek. Replace original bottle cap to maintain child resistance.

5. If needed, repeat dose every 6-8 hours.

Do not use more than 4 times a day.
 If stornach upset occurs while taking this product, give with

TOOL OF HIME.		
WEiGHT cor	AGE ,r	DOSE
Under 24	Under 2	Consult Doctor
24 - 35	2-3	2 Dropperfuls (2 x 1.25 ml.)

Attention: Specially designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other desing device.

WARMINGS

ALLEMATE REACTIONS: Children's Motrin may cause a severe allergic reaction which may include:

- · wheezing (asthma)
- · shortness of breath
- hives
- · swelling of the face
- · last, irregular pulse or heartbeat

· changing color of the skin (shock)

ASPIRIN-SENSITIVE PAYIENTS: Although Children's Motrin does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people altergic to aspirin or other pain relievers/lever reducers. Any of these reactions could be seriess. Step using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without prior reaction to Children's Motrin or other pain retievers/lever reducers.

(See Side Panel to the Right for Additional Warnings)

#### WARNINGS (continued) CALL YOUR DOCTOR IF

- · Your child is under a doctor's care for any serious condition or is taking any other drug.
- · Your child has problems or surious side effects from taking fever reducers or pain reflevers.
- Your child does not get any reliet within first day (24 hours) of treatment, or pain or fever gets worse. Stomach upset gets worse or
- lasts.
- Redness or swelling is present in the painful area.
- Sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting
- · Any new symptoms appear. DO NOT USE
- . With any other product that contains ibuprofen, or any other pain reliever/fever reducer. unless directed by a doctor.
- For more than 3 days for fever or pain unless directed by a doctor.
- For stomach pain unless
- directed by a doctor. If your child is dehydrated (significant tluid loss) due to continued vomiting, diarrhea or tack of fluid intake.
- If plastic bottle wrap imprinted "Safety Seal®" and "Use With Enclosed Dropper Only" is brokes or missing.

(See Opposite Side Panel for Additional Warnings).

# IBUPROFEN ORAL SUSPENSION

For Ages 2-3

BURROLL ORAL SUSBENSION

Read Instructions Carefully Child-Resistant Safety Cap



#### WARNINGS (continued) IMPURTANT:

- Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and could cause sorkus health problems. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek protessional assistance or contact a poison control center immediately.

#### Questions or Comments? Call toll free 1-800-962-5357

Or ask your Pharmacist. Doctor or other Health Care Professional.

See bottom of box for lot number and expiration date Stere at room temperature: 15 -38 C (59 -86 F)

Inactive Ingredients: Citric acid, cornstarch, FD&C Red #40, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

**Use Only** 

**Enclosed** 

Dropper

With

McNEIL CONSUMER PRODUCTS CO. DIVISION OF MCNEIL-PPC, INC FORT WASHINGTON, PA 19034 USA

MeNEIL

CMcN-PPC, Inc. '98 U.S. Patent No. 5,374,659



BERRY-FLAVORED DROPS

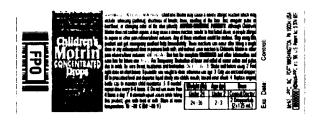
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WARNINGS --- ALLERGIC REACTIONS. Children's Motrin may cause a severe allergic reaction which may include: wheezing (asthma); shortness of breath; hives; swelling of the face; fast, irregular pulse of heartbeat; or changing color of the skin (shock). ASPIRIM-SENSTINE PATIENTS: Although Children's heartheat, or changing color of the stan (shock). ASPIRIM-SERSTIVE PATERITS: Although Children's Motin does not contain agoinn, it may cause a severe reaction, similar to that listed above, in people altergit to aspirin or other pain relievers/lever reducers. Any of these reactions could be serious. She using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motin or other pain relievers/lever reducers. IMPORTANT. See hox for complete MARIMINGS and other information and save hox for future use. USES: For Temperary: Reduction of four and relief of minor aches and paint due to colds, thu, sore throat, headraches and toothaches. DIRECTIONS. 1. Shake well before using, 2. Find right dose or chart below. It possible, use weight to dose; otherwise use age, 3. Only use enclosed dropper till to prescribed level and dispense liquid slowly into childs mouth, toward inner cheek. 4. Replace original hottle can be maintain child resistance. 5. If needed.

bottle cap to maintain child resistance. 5. If needed, repeal close every 6-8 hours. 6. Do not use more than 4 times a day. 7. If stomach upset occurs while taking this product, give with food or milk. Store at reem temperature: 15-30-0 °C (59-86-F).

Under 24 Under 2 | Consult Doctor 2 Dropperfuls (2 x 1.25 mL) 24-35 2-3

Date:

Œ.

NDA No: Reviewed by:

He'd

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IMPORTANT: Read all product information before using. Keep this bex for important information. This product is intended for use in children only.

ACTIVE INGHEDIENT: Ibuprofen.

USES For Temperary: • Reduction of fever

Relief of miner aches and pains due to colds, flu, sore throat, headaches and toothaches

DIM CHORS

 Shake well before using.
 Find right dose on chart below. If possible, use weight to dose; otherwise use age.

3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek.

4. Replace original bottle cap to maintain child resistance.

5. If needed, repeat dose every 6-8 hours.

 Do not use more than 4 times a day.
 If stomach upset occurs while taking this product, give with food or milk

nder 2	Consult Doctor
MOI 2	Consur Doctor
2-3	2 Droppertuls (2 x 1 25 mL)
	2-3

Attention: Specially designed for use with enclosed drapper. Use only enclosed drapper to dose this product. Do not use any other desing device.

WARRINGS

ALLERGIC LEACTIONS: Children's Motrin may cause a severe allergic reaction which may include:

wheezing (asthma)

· shortness of breath

hives

swelling of the face

· fast, irregular pulse or heartheat

changing color of the skin (shock)

ASPIRIM-SENSITIVE PATIENTS: Although Children's Motrin does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people altergic to aspirin or other pain relievers/lever reducers. Any of those reactions could be serious. Step using this product and get emergency medical help immediately. These reactions can occur after tak-ing a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motim or other pain relievers/lever reducers.

(See Side Panel to the Right for Additional Warnings)

WARNINGS (continued) CALL YOUR DOCTOR IS

- . Your child is under a doctor's care for any serious condition or is taking any other drug.
- Your child has problems or serious side effects from taking fever reducers or pain relievers.
- · Your child does not get any relief within first day (24 hours) of treatment, or pain or fever
- gets worse.
   Stomach upset gets worse or lasts.
- · Redness or swelling is present in the painful area.
- Sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vorniting
- Any new symptoms appear. DO NOT USE
- · With any other product that contains ibnorolen, or any other pain reliever/lever reducer. unless directed by a doctor.
- For more than 3 days for lever or pain unless directed by a doctor.
- · For stomach pain unless directed by a doctor.
- If your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea or lack of fluid intake.
- If plastic bottle wrap imprinted "Safety Seal®" and "Use With Enclosed Dropper Only" is broken or missing.

(See Opposite Side Patiet to: Additional Warnings)

## CONCENTRATED Drops

BUPROFEN ORAL SUSPENSION Read Instructions Carefully Child-Resistant Safety Cap

For Ages 2-3

IBUPROFEN GRAL SUSPENSION 59 ma per 1-25 ml (drepperiul)

Lasts up to 8 hours



Use Only With Enclosed Dropper

BERRY-FLAVORED DROPS

Or ask your Pharmacist, Doctor or other Health Care Professional.

> See bottom of box for lot number and expiration date. Store at room temperature: 15 -30 C (50 -86 F)

WARNINGS (continued)

Do not exceed recommended

recommended dose (overdose)

and could cause serious health

children. In case of accidental

assistance or contact a poison

overdose, seek professional

control center immediately.

Ouestions or Comments?

-800-962-5357

Call toll free

dose. Taking more than the

may not provide more relief

problems. Keep this and all

drugs out of the reach of

IMPORTANT.

Inactive Ingredients: Citric acid, cornstarch, FD&C Red #40. artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

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McNEIL CONSUMER PRODUCTS CO. DIVISION OF McNEIL-PPC INC. FORT WASHINGTON, PA 19034 USA CMcN-PPC Inc '98 U.S. Patent No. 5,374,659

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WARNINGS ALLENGIC REACTIONS Children's Motrin may cause a severe allergic reaction which may include: wheeing (ashma); shortness of breath; bives; swelling of the face; fast, irregular pulse of heartheat, or changing order of the skin (shock). ASPRIAL-SELSTIVE PATERIES: Although Children's Motrin does not contain asprin, it may cause a severe reaction, similar to that fisted above, in people allergic to asprin or other pain reflevers/fever reducers. Any of these reactions could be serious. Shop using this product and get emergency medical help immediately. These reactions can occur after taking a ingle dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain reflevers/fever reducers. INFORTANT See how for complete MARNINGS and other information and save host for father use. ISES For Temporany, Production of fever and relief of miner aches and pained due to colds, flu, sore throat, headaches and toothaches. ORECTIONS 1. Shake well before using 2. Find to prescribed level and dispense liquid slowly into child's mouth, toward inner check 4. Replace original bottle cap to maintain child resistance. 5. If needed, repeat dose every 6-6 hours, 6,00 not use more than 4 times a day, 7 if stomach upset occurs while taking this product, give with food or milk. Share at reem temperature: 15°-30°C (50°-36°F).

12 HYDRY KOMBIG BUSS CHSSS: 4: Uchiacs cultural			
Weight (lb)	Age (pr)	Dese	ľ
Under 24	Under 2	Consult Doctor	l
24-35	2-3	2 Dropperfuls (2x125 mL)	

MICHEIL-PPC, INC., FORT WASHINGTON, PA 19034 USA [0000000]@MICH-PPC, Inc. '98, U.S. Parent No. 5,374,659 Exp. Date:

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#### Principal Display Panel-carton

Infants' Motrin CONCENTRATED

Drops

For ages 6 months to 23 months

#### IBUPROFEN ORAL SUSPENSION

50 mg per 1.25 mL (dropperful)

#### Fever Reducer/Pain Reliever

Lasts up to 8 hours

Use Only With Enclosed Dropper

See New Label

#### **BERRY-FLAVORED DROPS**

Alcohol Free

1/2 FL OZ (15 mL)

#### Back Panel

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 months to 23 months of age.

### Drug Facts

Active ingredient (in each 1.25 mL)

Purposes

Ibuprofen 50 mg......Fever reducer/pain reliever

#### Uses temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

#### Drug Facts (continued)

#### Warnings

Allergy alert: ibuprofen may cause a severe allergic reaction which may include:

hivesfacial swellingasthma (wheezing)

Sore throat warning: severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

#### Do not use

• if the child has ever had an allergic reaction to any pain reliever/fever reducer

#### Ask a doctor before use if the child has

- not been drinking fluids
- lost a lot of fluid due to continued vomiting or diarrhea
- stomach pain
- problems or serious side effects from taking fever reducers or pain relievers

#### Ask a doctor or pharmacist before use if the child is

- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

#### When using this product give with food or milk if stomach upset occurs

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- fever or pain gets worse or lasts more than 3 days
- the child does not get any relief within first day (24 hours) of treatment
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

- do not give more than directed
- shake well before using
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- use only with enclosed dropper. Fill to dose level. Do not use any other dosing device.
- dispense liquid slowly into the child's mouth, toward inner cheek
- replace original bottle cap to maintain child resistance
- if needed, repeat dose every 6-8-hours
- do not use more than 4 times a day

#### **Dosing Chart**

Weight (lb)	Age (mos)	Dose (mL)
Under 6 mos		call a doctor
12 - 17 lbs	6-11 mos	1 dropperful (1.25 mL)
18 - 23 lbs	12-23 mos	1 ½ dropperfuls (1.875 mL)

Attention: Specifically designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing device.

Other information store at 20-25°C (68-77°F)

Inactive ingredients artificial flavors, citric acid, corn starch, FD&C Red #40, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

#### **■**Questions or Comments?

Call toll-free 1-800-962-5357

Or ask your Pharmacist, Doctor or Health Care Professional See bottom of box for lot number and expiration date

McNeil Consumer Healthcare DIVISION OF McNeil-PPC, Inc. FORT WASHINGTON, PA 19034 USA U.S. Patent No. 5,374,659